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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

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April 11, 2002

E. EDWARD KAVANAUGH
PRESIDENT

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

Citizen Petition: Docket No. 78N-0064

Dear Sir or Madam:

This petition is submitted by The Cosmetic, Toiletry, and Fragrance Association (hereafter "CTFA") under 21 CFR Part 10.30 of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to take the following actions regarding 21 CFR Part 350, the Tentative Final Monograph for OTC Antiperspirant Drug Products (hereafter the "Antiperspirant Monograph"). In the alternative, should the Agency choose to publish the final Antiperspirant Monograph before acting on this Citizen Petition, CTFA requests FDA to consider this as a petition to reopen the final monograph to consider the relief requested below.

This petition is filed to request that the Agency take action to permit the use of modified versions of the format and content requirements of the OTC Drug Labeling Regulation for antiperspirant products. CTFA is filing this petition as a request to amend the Antiperspirant Monograph in order to comply with an FDA request that all requests for relief from the OTC Drug Labeling Regulation for specific product categories be considered under the monograph for that category rather than as a request to amend the OTC Drug Labeling Regulation itself.

This request is consistent with the approach to similar labeling issues under consideration by FDA for sunscreen and skin protectant drug products. Similar relief has been granted under the Final Monograph for Sunscreen Drug Products for lipsticks containing sunscreen and for sunscreen products labeled for use on specific small areas of the face. FDA is currently considering requests for modified labeling requirements for additional sunscreen drug products as part of its current effort to develop proposed amendments to the Sunscreen Drug

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Monograph scheduled for publication later in 2002. In addition, FDA has stated that the final monograph for Skin Protectant Drug Products will provide for reduced labeling for certain products. That final monograph is scheduled to be published later this year.

In addition, in its January 18, 2002 response to a Citizen Petition by Lil' Drug Store Products, Inc. seeking relief from the OTC Drug Labeling Rule, FDA indicated that it intends to prepare a proposed rule that would amend the final OTC Drug Labeling Rule by (1) defining "convenience size" drug packages and addressing labeling requirements for those packages and (2) deferring the compliance date for labeling them. We support FDA's conclusion that these issues regarding convenience sizes for all drug products, including antiperspirants, need to be addressed, but believe that broader relief for antiperspirants is justified for the reasons stated in this petition. CTFA will comment under separate cover on the planned approach to convenience sizes.

ACTION REQUESTED

CTFA requests that FDA amend proposed 21 CFR Part 350, the Tentative Final Monograph for OTC Antiperspirant Drug Products, to permit the use of modified labeling in order to comply with the requirements of the OTC Drug Labeling Rule for antiperspirant drug products.

STATEMENT OF GROUNDS

While considered drugs instead of cosmetics because the antiperspirant ingredient affects the structure or function of the body by reducing perspiration, antiperspirant products are the kind of personal care product for which the very difficult format and content requirements of the OTC Drug Labeling Regulation are neither necessary nor appropriate. In fact, the requirements of the Rule are counterproductive because they will likely reduce the availability of the very products the Agency is trying to help the consumer use.

Antiperspirants are virtually always formulated in combination with a deodorant, a cosmetic product with the intended use of reducing or masking odor. Thus, they are cosmetic-drugs, but they are purchased by consumers primarily because of their cosmetic benefit – reduction of undesirable odor. Antiperspirant/Deodorants are used by consumers as a personal care product that provides a cosmetic benefit to a vast majority of the population as part of their daily routine of good hygiene.

In addition, many antiperspirants or antiperspirant/deodorants are marketed in small packages to permit easy use by today's highly mobile population. They come in many forms – stick, solid, gel, aerosol and others – and the current

marketplace for these products offers consumers a wide variety of choices of product form and convenient package sizes to choose from. Most are sold without secondary packaging. Therefore, many packages are unable to accommodate the requirements of the OTC Drug Labeling Rule without being made larger or more awkward. Without the relief sought herein, many of the more convenient forms of these products may disappear from the marketplace.

In the final OTC Drug Labeling Rule, FDA described the following construct for developing appropriate drug labeling:

> "(w)hen developing drug labeling, the agency considers the risks and benefits of the drug, the intended use, and the need to communicate limitations or restrictions about the use of the product to the target population. The quantity and complexity of information which must be communicated to ensure appropriate product selection, convey the effectiveness of the drug, communicate risks, and provide appropriate directions of use, varies with the drug ingredient, the target population, the disease or symptoms the product is intended to treat or prevent, and related information about the conditions which must be provided for the safe and effective use of the drug. In some cases (e.g., lipsticks or lip balms containing sunscreen), minimal information is needed for the effective use of the product."

CTFA submits that this analysis also leads clearly to the conclusion that antiperspirants require only minimal information for the safe and effective use of the product.

In the OTC Drug Labeling Regulation, FDA also listed the typical characteristics of products requiring minimal information for safe and effective use as follows:

- Packaged in small amounts;
- Having a high therapeutic index;
- Carrying extremely low risk in actual consumer use situations;
- Providing a favorable public health benefit;
- Requiring no specific dosage limitation; and
- Requiring few specific warnings (e.g. *Reyes syndrome*) and no general warnings (e.g., pregnancy or overdose warnings).

The Agency indicated its intent to "identify products with these characteristics" and "consider appropriate exemptions in their respective monographs and drug marketing applications to the extent possible." Id. CTFA believes that antiperspirants fit within the parameters of these criteria and fully justify the labeling modifications requested herein.

Antiperspirants are typically packaged in small amounts. Although there are larger package sizes available, the majority of antiperspirants are packaged in amounts of 3 ounces or less.

Antiperspirants have a high therapeutic index. The effective dose is substantially lower than the dose that would pose even a minimal risk of toxicity.

Antiperspirants carry an extremely low risk in actual consumer use situations. These products are used by more than 90 percent of the U. S. population and have a long history of safe use. Skin irritation, the only consumer side effect associated with the use of antiperspirants, is usually mild and temporary.

Antiperspirants provide a favorable public health benefit. The fact that use of these products provides a benefit is confirmed by the fact they are used by well over 90% of the population. They are part of a regimen of good hygiene, which is generally recognized as one of the elements of reducing the risk of disease.

Antiperspirants require no specific dosage limitation. These products are sold in a variety of forms, including sticks, gels, roll-ons and aerosols. None of the forms available require dosage limitations, and the great consumer familiarity with these products and their high level of safety allows the consumer to determine the amount necessary to be applied.

Antiperspirants require few specific warnings and only one general warning. The only specific warnings proposed for antiperspirants have to do with concerns related to skin irritation and a very specific caution about aerosols. The Tentative Final Monograph proposes a warning "Do not apply to broken skin. If rash or irritation develops, discontinue use." In addition, for products in an aerosolized dosage form, "Avoid excessive inhalation" is proposed. The only general warning required is the warning to keep out of reach of children and to get medical help or contact a Poison Control Center if swallowed. This would remain a part of the required labeling under the CTFA proposal.

FDA's General Rationale for the Final OTC Drug Labeling Rule Does Not Apply to Antiperspirants

Analysis of the rationale underlying FDA's OTC Drug Labeling Regulation supports CTFA's claim that, as with other cosmetic-drug products, there is a fundamental distinction between antiperspirant products and other OTC drug product categories. From the beginning of its rulemaking, FDA's rationale for standardizing the format and content requirements for all OTC drug products has been that it is necessary to enable consumers to better read and understand OTC drug product labeling and to apply this information to the safe and effective use of such products. See 64 Fed. Reg. 13254. However, nowhere in the records supporting the final OTC Drug Labeling Rule or the Antiperspirant Monograph is there any evidence that consumers are unable to read or understand information necessary for the safe and effective use of antiperspirants as currently labeled. The concerns expressed regarding several other OTC drugs do not exist for antiperspirants.

For example, FDA articulated the following "changing patterns" of OTC drug use as among its justifications for standardizing OTC drug labeling:

- Concerns about the increased availability of more potent medicines;
- Concerns about increased consumer self-diagnosis and self-medication;
- Concerns about the possibility of increased or inappropriate use of OTC drug products by the elderly; and
- Concerns regarding the possibility of increased adverse reactions and misuse of OTC drug products.

Over-the-Counter Human Drugs; Proposed Labeling Requirements; Proposed Rule. 62 Fed. Reg. 9024 (February 27, 1997). However, none of these justifications for imposing massive relabeling requirements have any application to antiperspirant products.

- Increased availability of more potent medicines should not be a concern of antiperspirant users. New product forms exist and manufacturers will always seek more effective products, but these are antiperspirants, not more potent medicines that may pose any legitimate concern of overdose or accidental misuse. They pose no increased risk to consumers.
- Increased consumer self-diagnosis and self-medication is not a major worry when it comes to antiperspirants. Since antiperspirants do not treat a disease, self-diagnosis and self-medications are not relevant concerns.

Over 90% of the population has been taking precautions against underarm perspiration for years. If the remaining population chooses to do so, it should be encouraged, not thwarted by labeling requirements that could eliminate the more convenient forms and sizes of these products.

- Similarly, increased or inappropriate use of OTC drug products by the elderly is not a concern for antiperspirants. Elderly persons who use antiperspirants probably have been using them for years. There are no dosage limitations, and there should be no concerns about using too much product.

- Finally, as stated above, adverse reactions are mild and infrequent and easily remedied by discontinuing use. Because there are no dosage limitations, no concerns about drug interactions, and no concerns about possible harm from overdoses, the threat from misuse is not of the same magnitude as it might be from other drugs.

The bottom line is that antiperspirants are fundamentally different from most other OTC drugs. They are topically applied, they contain ingredients that have a long track record of safety, and, although technically drugs, they are used – often in combination with deodorants - for a purpose that is primarily cosmetic.

FDA's Proposed Antiperspirant Label

Under FDA's Final OTC Drug Labeling Regulation, all antiperspirant products would be required to be labeled in accordance with the following model no later than May 16, 2005, assuming that the Final Antiperspirant Monograph is published after May 16, 2002. (This has been prepared in the absence of any specific guidance from FDA for the antiperspirant drug category.):

Drug Facts
Active ingredient ***Purpose*** Aluminum chlorohydrate 20%.....Antiperspirant
Use reduces underarm perspiration
Warnings **For external use only**
Do not use • on broken skin
Stop use and ask a doctor if • rash or irritation develops
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions apply to underarms only
Inactive ingredients cyclomethicone, stearyl alcohol, hydrogenated castor oil, talc, PPG-14 butyl ether, triclosan, ethylene brassylate, aloe barbidensis leaf juice, allantoin

CTFA's Proposed Antiperspirant Label

Active ingredient...Aluminum chlorohydrate 20%
Use reduces underarm perspiration
Warnings

- Do not use on broken skin
- Stop use if rash or irritation develops

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions apply to underarms only
Inactive ingredients cyclomethicone, stearyl alcohol, hydrogenated castor oil, talc, PPG-14 butyl ether, triclosan, ethylene brassylate, aloe barbidensis leaf juice, allantoin

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Note: The label illustrated above is intended to provide a simple "picture" of the proposed label that would apply to all antiperspirant products regardless of package size. (Of course, any additional modifications permitted by FDA for smaller packages or "convenience sizes" would also be available for such products.) The proposed antiperspirant product label incorporates the modified format provisions that allow for the elimination of the box enclosure as well as other modifications cited in 21 C.F.R. Sec. 201.66(d)(10). There has been no attempt to duplicate the type size requirements in this illustration.

The labeling language used above is for demonstration purposes only. To the extent the Final Monograph for Antiperspirant Drug Products permits the use of different statements or claims, this proposal is not intended to limit such options. Similarly, the above proposal does not include optional statements that may be permitted, nor have statements required for aerosol or other dosage forms been incorporated into the above proposal.

CTFA's Proposed Antiperspirant Label Ensures Proper Consumer Information in a Form Consistent with FDA's OTC Drug Labeling Rule

CTFA's proposal maintains the important content and format elements that would be required under the OTC Drug Labeling Rule:

- Active ingredient information and concentrations are provided
- Use information is preserved
- The "Warning" heading is preserved
- "Keep out of reach of children" and poison control statements are preserved
- Direction information is identical to that proposed by FDA

- All headings and information:
  - are presented in the required order;
  - would use the required type size;
  - use the proper letter case;
  - are justified as specified in the rule;
  - are presented in bold or italic print as appropriate; and
  - use bullets appropriately.

The format changes proposed by CTFA for antiperspirants are limited to the following:

- Elimination of the "Drug Facts" heading;
- Elimination of the "Purpose" heading and related information;
- Elimination of the "For External Use Only" statement;
- Condensing of warning subheadings and statements; and
- Elimination of the box enclosure, barlines and hairlines.

Arguments Supporting the CTFA Labeling Proposals

1. Elimination of the "Drug Facts" Heading

The requirement that the title "Drug Facts" appear at the top of the information panel should be eliminated for antiperspirant products. It is unnecessary, and reduces the space available for important label information. For products that are often sold in combination with a deodorant and also regulated as a cosmetic, the term "Drug Facts" is even misleading. Elimination of this requirement is entirely consistent with the action already taken by FDA to eliminate the "Drug Facts" requirement for sunscreens labeled for use only on specific small areas of the face.

2. Elimination of the "Purpose" Heading and Associated Information

CTFA's proposal does not include the "Purpose" heading or associated information. This is unnecessary and redundant to the statement of "Use" that is retained and would appear immediately after the purpose. That "Use" statement tells consumers that the product "reduces underarm perspiration." Elimination of this information is also consistent with action already taken by FDA to eliminate the "Purpose" requirement for sunscreens labeled for use only on specific small areas of the face.

3. Elimination of the "For External Use Only" Statement

This information is not necessary due to widespread consumer knowledge and understanding of the proper use of antiperspirants. We are unaware of any information suggesting that consumers inappropriately apply antiperspirants. This action is also consistent with action taken by FDA for sunscreens labeled for use on small areas of the face.

4. Consolidation of Warning Language

CTFA proposes that language in subheadings required by the OTC Drug Labeling Regulation be consolidated into one line with warning language for antiperspirants. For example:

Do not use

- on broken skin

would become

Do not use on broken skin

This modification was also allowed for sunscreens labeled for use on small areas of the face. It still clearly presents the necessary information to consumers and eliminates the unnecessary use of extra lines.

CTFA believes that the currently required subheading information and warning language is not necessary for full consumer understanding of the warning information or for the safe and effective use of antiperspirant products. The information contained in CTFA's proposed antiperspirant label is substantively the same as that provided by the separate subheadings and retains the hierarchy of FDA's preferred format. Similar modifications of warning language were allowed by FDA in regulations pertaining to sunscreen products labeled for use on small areas of the face. 21 CFR Sec. 352.52(f)(1)(iv).

Proposed Format Changes

CTFA's proposal would eliminate unnecessary formatting requirements while preserving the "power" of FDA's new labeling requirements to assist consumers in making appropriate product choices. In a February 4, 2000 letter to CTFA, Associate Commissioner William K. Hubbard stated the following:

> The new format establishes a clear, easy-to-read presentation that lists the required information in a logical hierarchy, with simple headings and to introduce major sections of the labeling. The format also includes minimum type size and graphical standards, to

ensure that consumers are able to read the required labeling comfortably from beginning to end. And, the format is designed to allow consumers to compare similar products side-by-side, to help them select the best product to meet their needs.

The CTFA proposal preserves critical elements of the format and will allow consumers to compare any antiperspirant with any other antiperspirant with respect to all information that is critical to product purchase.

CTFA's proposed antiperspirant label will maintain the following format requirements:

- Use of upper and lower case letters;
- Justification of information as specified in the rule;
- Type size;
- Use of bold and italic type; and
- Use of bullets.

On the other hand, CTFA is requesting that certain format requirements that greatly increase the difficulty of compliance, particularly for smaller packages, be eliminated. The following would not be required for antiperspirants:

- The box enclosure;
- Bar lines; and
- Hair lines

Removal of these requirements in no way interferes with the ability of the consumer to understand and act appropriately on the information presented, nor does it prevent consumers from making the product comparisons emphasized by Mr. Hubbard.

Conclusion

We urge FDA to adopt the CTFA proposals for more flexible labeling for all antiperspirant products. Antiperspirants are personal care products, most often sold in combination with deodorants. They have no dosage limitations, have a long record of safe use and are used by an extremely large percentage of the American public. In order to facilitate their use, they are often packaged in smaller packages or in convenience sizes designed for travel.

CTFA has proposed labeling requirements for these unique products that includes all critical information and format requirements of the OTC Drug

Labeling Regulations while recognizing the need for packaging that could not continue to exist without this labeling flexibility.

We urge FDA to amend the Antiperspirant Monograph to permit this flexibility for antiperspirants in complying with the OTC Drug Labeling Rule.

ENVIRONMENTAL IMPACT

According to 21 CFR 25.31(c), this petition qualifies for a categorical exclusion from the requirement that an environmental assessment be submitted.

ECONOMIC IMPACT

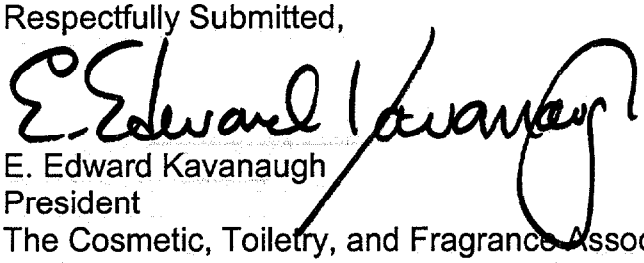
According to 21 CFR 10.30(b), information on economic impact is to be submitted only when requested by the Commissioner following review of the petition.

CERTIFICATION

The undersigned certify that, to the best of their knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data known to the Petitioner, which are unfavorable to the petition.

Thank you for your consideration of this petition.

Respectfully Submitted,



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